Responses to Questions - Solicitation RFP-NIH-NIAID-DMID-PR2004-02
Recombinant Type E Botulinum Neurotoxin Vaccine

Q1. Page 5 of 29 - Statement of Work Paragraph C Period of Performance and Budgets. It is indicated that the estimated maximum budget is $3M. If all milestones identified on Page 4 of 29 cannot be accomplished for $3M, what is the recommended approach by NIAID? Does NIAID anticipate that additional funding will be made available?

Answer: The offeror should propose the amount of cGMP Vaccine that they can produce for $3 million while meeting all other milestones contained in the Statement of Work.

Q2. Page 12 of 29 - For purposes of clarification, the maximum page limitation for both the Technical Volume and the Business Volume combined is 50 pages total excluding Representations and Certifications. Please confirm.

Answer: No, the 50-page limit does not include the Rep & Cert.

Q3. Page 15 of 29 - Section L Paragraph 1.b General Information, Type of Contract and Number of Awards. It is indicated that the award from this solicitation will be a FIXED PRICE type of contract but on Page 25 of 29, Paragraph 3 (d), Other Administrative Data, Incremental Funding, a cost reimbursement type of contract is referenced. In addition, the RFP includes in full text the HHSAR Incremental Funding clause (HHSAR 352.232-75). This clause states “the Government will not be obligated to reimburse the Contractor for costs incurred in excess of the periodic allotments, nor will the Contractor be obligated to perform in excess of the amount allotted”. Will the award be made as a FIXED Price contract or a cost reimbursement type of contract? Please clarify.

Answer: The RFP is hereby amended to delete the HHSAR Incremental Funding clause in its entirety, since this award is for one year and it will be fully funded at the time of award.

Q4. Page 19 of 29 - Paragraph (8)(d)(f). While Page 1 of 9 Item 7, Number of Awards, indicates that “Only 1 Award” will be made, while Paragraph (8)(d)(f) indicates NIAID reserves the right to make multiple awards. Please clarify.

Answer: One award will be made from this RFP. The language in paragraph 8(f) is standard contractual language placed in all RFPs issued by all institutes at NIH. It states that the institute reserves the right to make a single award, multiple awards, or no award at all to the RFP. That is not to be interpreted as NIAID is to make multiple awards.

Q5. Page 28 of 29 - Section M-Evaluation Factors for Award Paragraph 2 Extent of Small Disadvantaged Business Participation. Although SDB participation will not be scored, the RFP includes as part of the FAR clauses, FAR 52.219-16, Small Business Subcontracting Plan. Will the Contractor be required to submit a Small Business Plan as part of its Business Proposal? If yes, can the Contractor include the plan as part of the Proposal Appendices?

Answer: The Small Business Subcontracting Plan is not required at the time of submission of the proposal. However, the successful offeror (if a Large Business) will be required to prepare and submit one at a later time.

Q6. Can the Contractor provide the Basic Cost/Price Information in it's own format, or are we required to use the online NIAID Excel Workbook? (Note that the NIAID Workbook would need to be modified significantly to break down the costs by month and milestone.)

Answer: The offeror can provide cost information using their own format.

Q7. Page 4 of 29 – Stability testing of cGMP bulk drug substance and drug product is requested six months after production. Does this imply that only release testing and six month stability testing is required or is stability testing to be conducted according to ICH Guidelines at 3 and 6 months?

Answer: Stability testing should be conducted according to ICH Guidelines.

Q8. The period of performance is 12 months including submission of stability testing data for six months of stability testing. This implies that cGMP bulk drug substance and final drug product must be manufactured no later than approximately six months following award of the contract. Is it acceptable to utilize the 12-month period of performance to manufacture product and then place the material to be manufactured on stability testing? Please clarify.

Answer: Deliverables will be accepted up to 90 days outside the 12 month period of performance.

Q9. Page 4 of 29 - A Phase 1 Clinical Trial is typically a dose-escalating study, where each cohort receives the next higher dose level of vaccine. To formulate the drug product, the amount of antigen and adjuvant in a unit volume will need to be defined. What is the composition of the 2000 doses of drug product to be provided by the Contractor?

Answer: The composition of the 2000 doses of drug product to be provided by the Contractor should be based on an estimated concentration of the formulated product based on preclinical immunogenicity data and/or knowledge of similar products.

Q10. Page 4 of 29 - What is expected from the Contractor for technology transfer of analytical assays? Are detailed reports for each of the stability testing assays sufficient?

Answer: The Offeror should propose a plan for technology transfer that demonstrates they have considered all aspects necessary to successfully transfer technology developed under the

contract. The strength of the plan for technology transfer will be evaluated as part of the overall proposal.

Q11. Page 5 of 29 - To determine shipping costs, we will need to know where to ship the cGMP bulk drug substance and drug product.

Answer: The offeror can estimate shipping costs based on the assumption of shipping to an address in Rockville, Maryland.

Q12. Page 5 of 29 - What is expected of the Contractor to support the IND submission to the FDA other than a CMC?

Answer: The contractor may be requested to provide any information related to product manufacturing and characterization as it relates to the filing of the IND and developing the Investigators Brochure.

Q13. Page 21 of 29 – The technical proposal should contain letter(s) that document access to the proposed starting material and specific data characterizing the starting material. What information should the letter contain and what specific data is required?

Answer: The Offeror should provide information sufficient to demonstrate that they will have timely access to the starting material. In addition, the offeror should provide sufficient data on the characterization of the proposed starting material to demonstrate the potency of the candidate vaccine in a small animal model. The ideal candidate will have demonstrated protection against a 1000 MIPLD50 challenge of type E toxin in a mouse protection assay.